

REMARKS

In response to the Office Communication of January 15, 2009, Applicants have removed the underlining of the newly added paragraph.

Applicants appreciate the examination of the present application as evidenced by the Office Action dated September 5, 2008 (hereinafter, "the Office Action"). Applicants have canceled Claims 1, 10-12 and 14 herein without prejudice in view of the restriction requirement, and Applicants reserve the right to file the subject matter of these claims in a divisional application.

Applicants further respectfully request further consideration of the application in view of the comments that follow to address the issues raised in the Office Action as set forth below.

I. Double Patenting

The Office Action asserts that present Claims 2-9, 13 and 15-22 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-12, 14-21 and 25 of co-pending U.S. Patent Application Serial No. 11/170,561 and Claims 1-12 and 14-21 of co-pending U.S. Patent Application Serial No. 11/170,371.

Applicants will provide a Terminal Disclaimer upon the indication that the claims of the present application are otherwise in condition for allowance.

II. Claim Rejections Under 35 U.S.C. §103

Claims 2-9, 13 and 15-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,352,844 to Maurer et al. (hereinafter, "Maurer et al.") in view of U.S. Patent No. 4,874,796 to Yesair (hereinafter, "Yesair I") or U.S. Patent No. 5,972,911 to Yesair (hereinafter, "Yesair II") and further in view of U.S. Patent No. 4,665,098 to Gibbs et al. (hereinafter, "Gibbs et al.") and U.S. Patent No. 4,327,116 to Weith (hereinafter, "Weith"). See Office Action, page 4.

To establish a *prima facie* case of obviousness, the prior art reference or references

when combined must teach or suggest all the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. §2143. A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U. S. 1, 15 (2007).

In this instance, the Office Action states that "taking the teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that modifying the composition of Maurer by using the carrier of Yesair I or II, and delivering the formulation as food item as suggested by Gibbs, the food item having been thickened by flour, would be easily administered to any patient including geriatric or pediatric patient." Office Action, page 6. However, a fair reading of the cited references reveals the following:

Maurer: Maurer does not teach the specific carriers recited in the claims as stated in the Office Action. *See* Office Action, page 5.

Yesair I and II: Both Yesair I and II are directed to lipid colloid compositions. *See* Yesair I, Col. 4, line 35 through Col. 5, line 46, and Yesair II, Col. 4, line 26 through Col. 5, line 33. The current method is directed to the use of a dry flowable powder as recited in the pending claims.

Gibbs et al.: Gibbs et al. is directed to a suspension including the active agent, corn oil and a non-ionic surfactant. *See* Col. 2, lines 4-16. Moreover, Gibbs et al. states, "the present invention comprises a novel dosage form of N-(4-hydroxyphenyl)retinamide This would allow administration of significantly smaller amounts of HPR to patients while achieving the desired blood levels of drug, as compared to administration of the drug in dry powder, tablet or aqueous suspension forms." Gibbs et al., Col. 1, lines 58-65 (emphasis added). Again, the current method is directed to the use of a dry flowable powder as recited in the pending claims.

Weith: Weith is directed to bakery products consisting predominantly of bran and a method of producing them. *See* Weith, Abstract. Weith clearly does not cure the deficiencies

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of the previously cited references.

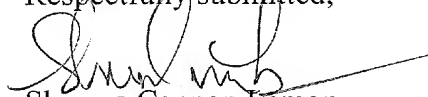
At least in view of the foregoing, Applicants respectfully submit that one of ordinary skill in the art would not look to these cited references in order to arrive at a method employing a **dry powder** formulation. Even if one were to combine the references, in view of the deficiencies as noted above, the references would not provide the present invention. Moreover, Gibbs et al. actually **teaches away** from a dry powder composition directing one of ordinary skill in the art to a suspension including corn oil, among other things.

Accordingly, Applicants respectfully submit that Claims 2-9, 13 and 15-22 are not obvious in view of the cited references, and Applicants respectfully request that the obviousness rejection of the claims be withdrawn.

CONCLUSION

Accordingly, Applicants submit that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any small matters outstanding of resolution, the Examiner is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

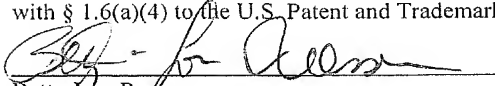


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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on January 26, 2009.


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